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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/737,324	12/16/2003	Edward H. Cully	MP/179	5934

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EXAMINER	
CHATTOPADHYAY, URMI	
ART UNIT	**PAPER NUMBER**
3738	

DATE MAILED: 05/10/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

5A

Office Action Summary	Application No.	Applicant(s)	
	10/737,324	CULLY ET AL.	
	Examiner	Art Unit	
	Urmi Chattopadhyay	3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 April 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-34* is/are pending in the application.

4a) Of the above claim(s) *7 and 24-28* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6,8-23 and 29-34* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *14 February 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *6/21/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Species 1b, claims 1-6, 8-23, 25 and 29-34 in the reply filed on 4/6/05 is acknowledged. The traversal is on the ground(s) that the various subspecies are defined erroneously, with Species 1a and 1b representing different means for splitting of the graft material during disassembly for removal of the device from a body conduit, while Species 1c and 1d represent different materials from which the graft may be constructed. Thus the devices might be provided with means for splitting as shown by either Figures 4A or 4B, while either of such devices might be made using the graft materials as such shown by Figures 4C or 4D. This is not found persuasive because according to the specification on page 6, lines 10-12, and page 10, line 22 to page 11, line 36, FIGS. 4A-4D are disclosed as various means for weakening the covering material. Therefore, they are all different means for splitting the graft material during disassembly for removal of the device from a body conduit. The requirement is still deemed proper and is therefore made FINAL. Accordingly, claim 25 has been withdrawn for being directed to non-elected Species 1c of Figure 4C. Claims 1-34 are currently pending, with claims 7 and 24-28 being withdrawn. The claims being considered for further examination on the merits are claims 1-6, 8-23 and 29-34.

Information Disclosure Statement

2. The information disclosure statement (IDS) filed on 6/21/04 has been entered. All references cited therein have been considered. A line has been drawn through one citation because it was a duplicate of a previous citation.

Specification

3. The specification is objected to. Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

On lines 2-3, "of the present invention" includes legal phraseology that must be removed.

Claim Objections

4. Claim 20 is objected to under 37 CFR 1.75(c), for failing to further limit the subject matter of a previous claim. Claim 20 appears to be same as claim 18, with respect to all claimed limitations. Applicant is required to cancel the claim(s) or amend the claim(s) to place the claim(s) in proper dependent form.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claim 34 is rejected under 35 U.S.C. 102(b) as being anticipated by Schwartz et al. (USPN 5,799,384 as cited in applicant's IDS).

Schwartz et al. discloses a method of making a removable stent-graft with all the elements of claim 34. See Figures 1-4 and column 5, lines 51-52 for providing a stent component (4) having a helical orientation having a pitch, and for providing the stent component (4) with a graft material (8) that covers one side of the stent component (4). See column 4, lines 65-67 for the graft material (8) overlapping adjacent stent elements (14), thereby covering the spaces between stent elements (14). Because the overlapped portions of the graft material (8) are not attached to each other, the graft material (8) is capable of being split (defined as "separated") in a direction parallel to the pitch of the helical orientation of the stent component (4).

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. Claims 1-6, 8-10, 12-15, 17-20, 22 and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schwartz et al. in view of Bosley, Jr. (USPN 5,514,176 as cited in applicant's IDS).

Schwartz et al. discloses an endoprosthesis with all the elements of claims 1 and 33, but is silent to the endoprosthesis being adapted to be cohesively disassembled to allow for its remote removal from a patient. See Figures 2-5 for an endoprosthesis (10) comprising a

structural support in the form of a stent component (4) having a small delivery profile (Figures 6 and 7) and an enlarged deployed profile (Figure 8), and adjacent elements (14) with space therebetween (Figure 5). A graft material (8) is attached to the stent component (4) covering the space between stent elements (14) to form a continuous luminal surface (column 4, lines 65-67). See Figure 5 and column 4, lines 48-50 for the stent (4) being in the form of a coil and column 5, lines 60-62 for the stent (4) being made from tantalum or stainless steel. Bosley, Jr. teaches a coil stent (10) made from tantalum or stainless steel that includes a tag end (22) for being gripped by forceps for the cohesive disassembly of the stent (10) for removal from the patient. See Figure 9, column 4, lines 46-49 and 65-65 and column 7, lines 7-9. It would have been obvious to one of ordinary skill in the art at the time of applicant's invention to look to the teachings of Bosley, Jr. to modify the stent component (4) of Schwartz et al. by including a tag end (22) on the end thereof that is grippable by forceps. Because the stent material (tantalum or stainless steel) of Schwartz et al. is the same as that of Bosley, Jr., the stent of Schwartz et al. is modified to include the tag end of Bosley, Jr., and the graft material (8) of Schwartz et al. has strain relief in the form of a slit or v-shaped cut, the endoprosthesis of Schwartz et al. is adapted to be cohesively disassembled for its remote removal from the patient.

Claim 2 includes only functional language and fails to further structurally limit the claimed invention The graft material (8) is capable of tearing, particularly at the point of the slit or v-shaped cut shown in Figure 3.

Claims 3-6, 8 and 9, see Figures 8 and 9 of Bosley, Jr. When the tag end applied to the stent of Schwartz et al. is gripped and pulled, the endoprosthesis (10) will be removable at a

profile less than the enlarge deployed profile and the small delivery profile by disassembling in a helical fashion in a single piece. The endoprosthesis will increase in length by at least 500%.

Claim 10, see column 4, lines 8-10 for the graft material (8) being impermeable.

Claims 12 and 13, see Figure 8 as compared to Figure 7 for the endoprosthesis (10) being adapted to be controllably foreshortenable by at least about 50%.

Claim 14, see rejection to claim 1, supra. Also see column 5, lines 51-52 for the graft material (8) being attached to the stent (4) and Figure 3 for the graft material (8) including slits of v-shaped cuts, thereby making the graft material (8) adapted to be cohesively disassembled during removal of the endoprosthesis from a patient.

Claim 15, see column 7, lines 21-23 of Bosley, Jr. for the removal being atraumatic.

Claims 17-20, see Figures 1-4, column 4, lines 37-50 and 65-67 for the graft material (8) comprising a tape, wherein the tape and stent component (4) are helically oriented at substantially the same pitch angle. Because the graft material (8) tape is overlapping adjacent stent elements (14) without being attached thereto, the tape is adapted for splitting (defined as "separating") along the length of the tape.

Claim 22, see Figure3 for the graft having means for splitting (defined as "separating") in the form of slits or v-shaped cuts.

9. Claims 11, 16 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schwartz et al. and Bosley, Jr. as applied to claims 1 and 20 above, and further in view of Smith (USPN 6,364,904).

Schwartz et al., as modified by Bosley, Jr., discloses an endoprosthesis with all the elements of claims 1 and 20, but is silent to the additional limitations of the graft material being permeable and comprising ePTFE, as required by claims 11, 16 and 21. Smith teaches an endoprosthesis in the form of a stent-graft, wherein the graft is made from ePTFE in order to provide the endoprosthesis with a microporous structure that allows natural tissue ingrowth and cell endothelialization for long term healing and patency of the graft. See column 1, lines 54-60 and column 9, lines 40-41. It would have been obvious to one of ordinary skill in the art at the time of applicant's invention to look to the teachings of Smith to modify the endoprosthesis of Schwartz et al. by making the graft from ePTFE, which is by nature permeable, in order to provide the endoprosthesis with a microporous structure that allows natural tissue ingrowth and cell endothelialization for long term healing and patency of the graft.

10. Claim 23 is rejected under 35 U.S.C. 103(a) as being unpatentable over Schwartz et al. and Bosley, Jr. as applied to claim 22 above, and further in view of Bigus et al. (USPN 6,629,992).

Schwartz et al., as modified by Bosley, Jr., discloses an endoprosthesis with all the elements of claim 22, but is silent to the means for splitting comprising a row of perforations extending through at least a portion of the thickness of the graft material, as required by claim 23. See Figure 3 and column 4, lines 38-46 for the means for splitting being a cut. Bigus et al. teaches an endoprosthesis wherein a sheath is provided with perforations (52) as an alternative to a cut (scoring 50) to provide the sheath with a weakened area at a desired location. See Figure 5 and column 7, lines 1-4 and 9-12. It would have been obvious to one of ordinary skill in the art

at the time of applicant's invention to look to the teachings of Bigus et al. to modify the endoprosthesis of Schwartz et al. by making the means for splitting a row of perforations extending through the thickness of the graft material (8) because it is a known alternative to a cut for providing a weakened area (strain relief) at a desired location.

11. Claims 29 and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schwartz et al. in view of Cully et al. (WO 00/42949 as cited in applicant's IDS).

Schwartz et al. discloses an endoprosthesis with all the elements of claim 29, but is silent to at least one of the apices being raised to protrude outwardly from the tubular form and wherein the resulting raised apex is covered by the graft material. See Figures 1-4 and column 4, lines 17-51 for an endoprosthesis (10) comprising a stent component (4) comprising a wire (2) formed into a generally helical winding having a space between adjacent elements (14) of the generally helical winding (Figure 5). The generally helical winding provides a generally tubular form to the stent component (4) and wherein the generally helical winding includes at least one apex (Figures 1-3). A graft material (8) is attached to the stent component (4) covering the space between adjacent elements (14) to form a continuous luminal surface (column 4, lines 65-67). Cully et al. teaches an endoprosthesis (10) wherein at least one apex (15) of the stent (11) is raised to protrude outwardly from the tubular form in order to provide as anchoring means by protruding slightly into the wall of the conduit into which it is implanted. See Figure 1 and page 6, lines 27-31. It would have been obvious to one of ordinary skill in the art at the time of applicant's invention to look to the teachings of Cully et al. to modify the endoprosthesis of Schwartz et al. by making at least one of the apices raised to protrude outwardly from the tubular

form in order to provide the endoprosthesis (10) with an anchoring means by the apex protruding slightly into the wall of the conduit into which it is implanted. Because the wire (2) forming the stent component (4) is attached to the graft material (8), and the graft material (8) overlaps adjacent elements (14) (column 4, lines 65-67), the raised apex will be covered by the graft material (8) while the graft material (8) continues to provide a continuous luminal surface.

Claim 31, see Figure 4 for the generally helical winding having a serpentine form with alternating opposing apices.

12. Claims 30 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schwartz et al. and Cully et al. as applied to claims 29 and 31 above, and further in view of Bosley, Jr.

Schwartz et al., as modified by Cully et al., discloses an endoprosthesis with all the elements of claims 29 and 31, but is silent to the endoprosthesis being adapted to be cohesively disassembled to allow for its remote removal from a patient. See Figure 5 and column 4, lines 48-50 for the stent (4) being in the form of a coil and column 5, lines 60-62 for the stent (4) being made from tantalum or stainless steel. Bosley, Jr. teaches a coil stent (10) made from tantalum or stainless steel that includes a tag end (22) for being gripped by forceps for the cohesive disassembly of the stent (10) for removal thereof from the patient. See Figure 9, column 4, lines 46-49 and 65-65 and column 7, lines 7-9. It would have been obvious to one of ordinary skill in the art at the time of applicant's invention to look to the teachings of Bosley, Jr. to modify the stent component (4) of Schwartz et al. by including a tag end (22) on the end thereof that is grippable by forceps. Because the stent material (tantalum or stainless steel) of

Schwartz et al. is the same as that of Bosley, Jr., the stent of Schwartz et al. is modified to include the tag end of Bosley, Jr., and the graft material (8) of Schwartz et al. has strain relief in the form of a slit or v-shaped cut, the endoprosthesis of Schwartz et al. is adapted to be cohesively disassembled for its remote removal from the patient.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Urmi Chattopadhyay whose telephone number is (571) 272-4748. The examiner can normally be reached on Tuesday-Thursday 10:00am - 6:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4754. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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